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ORIGINAL ARTICLE

New device for intraoperative graft assessment: HyperEye charge-coupled device camera system

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Abstract
Purpose. Our institution developed a new color charge-coupled device (CCD) camera system (HyperEye system) for intraoperative indocyanine green (ICG) angiography. The device consists of a combination of custom-made optical filters and an ultra-high-sensitive CCD image sensor with non-Bayer color filter array (i.e., HyperEye technology), which can detect simultaneously color and near-infrared (NIR) rays from 380 to1200 nm. Here, we demonstrate intraoperative graft assessment using the HyperEye system.
Methods. We investigated the intraoperative graft patency using both the HyperEye system and transit-time flowmetry (TFM) in 51 patients between April 2007 and April 2009 while ICG dye was injected through a central venous catheter. Each patient signed a consent form before the surgery.
Results. We obtained intraoperative graft flows and images in 189 anastomoses of 153 grafts. Both the HyperEye system and TFM indicated the patency of the grafts in 129 grafts. Both the HyperEye system and TFM detected the abnormality of the graft in seven grafts. For the competitive flows, the HyperEye system captured to-and-fro flow fluorescence and TFM detected the retrograde waveform in 16 grafts. On the other hand, although TFM indicated the patency of the graft, the HyperEye system suspected nonoccluded graft failure in seven grafts. In contrast, although TFM detected a mean flow of <10 ml/min, the HyperEye system captured the patent perfusion fluorescence in four grafts.
Conclusion. The HyperEye system can visualize any structural and functional failures. Our findings suggest that this device could become a useful tool for intraoperative graft assessment.

Key words Indocyanine green angiography · Coronary artery bypass graft · Intraoperative graft assessment · New device

Introduction

Several techniques have been employed to assess intraoperative and postoperative graft patency. We indicated that conventional angiography was a gold standard graft assessment tool for coronary artery bypass graft (CABG).[1,2] On the other hand, intraoperative conventional angiography was an invasive procedure; hence, most institutions perform transit-time flow measurement (TTFM) for intraoperative graft assessment. Although TTFM is an easy procedure,[3–5] it is unable to evaluate the graft patency with visual images.

The recent invention of an intraoperative indocyanine green (ICG) fluorescence imaging system (SPY; Novadaq Technologies, Toronto, Canada) has helped provide direct visual images during CABG,[6–11] thereby giving better diagnostic accuracy for detecting clinically signifi-

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cant graft errors than does TTFM.[12–14] The SPY system is an effective, highly reproducible method for achieving high-quality angiographic depiction of the graft, anastomosis, and target vessel, including nonocclusive stenosis.[9,11–14] On the other hand, the main drawbacks of SPY system are that ICG fluorescence images are captured by the monochromatic charge-coupled device (CCD) camera, and the continuous recording time is limited to 35 s because of the automatic laser shutoff.

To overcome these issues, our institution developed an advanced ICG fluorescence angiography system that captures ICG fluorescence images on a color CCD camera, illuminated with light-emitting diodes (LED) and, importantly, recording the images more than 5 min. We demonstrate the characteristics of this device, which can detect simultaneously color and near-infrared images during CABG, and we show the types of flow pattern that this device can image during CABG.

Materials and methods

Indocyanine green

Indocyanine green has been used in medicine for more than four decades. ICG is a water–soluble tricarbocyanine dye with a peak spectral absorption at 800–810 nm when dissolved in blood. After injection, it is rapidly bound to plasma proteins, thus remaining within the vasculature. When illuminated with 806-nm light, ICG fluoresces and emits light at 830 nm as previously described.[6] However, our preliminary in vitro study showed that the peak spectral absorption for ICG (0.001%) diluted in human blood was 760–780 nm (data not shown). Here, we selected a light source at 760 nm.

HyperEye CCD camera system (HyperEye system)

To clarify the technological difference between the conventional system and our system, we briefly describe the characteristics of the two systems. The SPY system uses a monochromatic CCD camera at 30 frames per second and displays the result on a computer monitor. A light source for excitation of ICG dye is the laser light, with an output of 2.0 W, and the laser light illuminates an area of 56 cm^2 (7.5 × 7.5 cm) of the heart. The camera/laser head is positioned above the area of interest at a distance of approximately 30 cm. The correct position is indicated by means of an automatic distance sensor, thus ensuring that the camera is at the correct focal length.[8]

The major difference between our new device and the SPY system is that the HyperEye system can visualize ICG-enhanced structures against a background of natural myocardium with vivid color (as shown in Figs. 2–5, below). The device consists of a combination of custom-made optical filters and an ultra-high-sensitive CCD image sensor with non-Bayer color filter arrays (i.e., HyperEye technology; United States Patent Application 20080251694), which can detect visible and near-infrared (NIR) rays from 380 to 1200 nm without a bias of color balance at 30 frames per second. A light source for excitation of ICG dye was made with an array of light-emitting diodes (LED) (760 nm). Importantly, the amount of heat produced during long time use of LED is negligible, making it easier and safer in clinical use. The low-angled ring LED light source decreases glare from the surface of the heart and the cells compared with using the same axle LED light, and its illumination area is 78.5 cm^2 (3.14 × 5.0 × 5.0 cm) on the surface of the heart and the cells.

For intraoperative image acquisition, the camera is positioned above the area at a distance of 30–50 cm. The focus, iris, and range are regulated by manual control, thus ensuring that the camera is at the free position. ICG dye (2.5 mg/ml) is injected through a central venous catheter in all patients. After injecting the ICG, image acquisition is initiated by means of single command to the computer. The movie is recorded using a conventional laptop computer, and the files are stored in avi format, which can be immediately replayed to the operating room. The HyperEye CCD camera is connected to the imaging monitor with the same axial cable, and the imaging monitor is connected to the laptop computer with a USB cable (Fig. 1).

The HyperEye system provides visualization in skeltonization arterial conduits and venous conduits as well as the SPY system, but we obtain better visualization in pedicled ones using our new device. The drawback of our new device is that color CCD camera does not visualize near-infrared (NIR) fluorescence from a deep intramyocardial coronary artery or a coronary artery embedded in the deep fatty tissue as well as the SPY system because NIR fluorescence cannot penetrate the thick tissues.

Patients

From April 2007 to April 2009, patients undergoing CABG performed by a single surgeon were included in this study, and off-pump coronary artery bypass graft (OPCAB) was a standard procedure for isolated CABG. Each patient signed a consent form before the surgery.

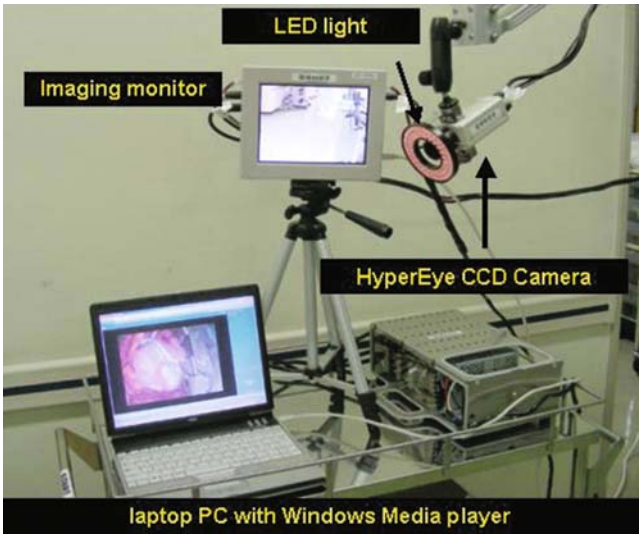

Fig. 1 Combination of custom-made optical filters and an ultra-high-sensitive color charge-coupled device (CCD) image sensor that can detect simultaneously color and near-infrared rays (NIRs). A light source for excitation of indocyanine green (ICG) dye is made with an array of light-emitting diodes (LEDs). Recording time is not limited, and a movie is recorded on the hard disk of the laptop computer

Exclusion criteria included allergy to ICG dye and cardiogenic shock.

Standard graft design

All patients underwent CABG via a median sternotomy. Our strategy for construction of the anastomosis was to graft the left internal thoracic artery (LITA) to the left anterior descending artery (LAD), the right internal thoracic artery (RITA) to the diagonal branch (Dx) or the circumflex artery (Cx) branch, and the saphenous vein graft (SVG) to the Dx or the Cx branch. The gastroepiploic artery (GEA) or the SVG was used to graft the posterior descending branch (4PD) of the right coronary artery (RCA). The sequential bypass was mainly performed with the long SVG, and the proximal anastomosis was performed with a partial aortic clamp.

Classification of the severity of a native coronary artery stenosis

For our study, we defined the severity classification as whether the target coronary artery has multiple stenoses (or not) in the proximal portion; severe stenosis means there was ≥90% stenosis in at least one portion, and moderate stenosis means the target coronary artery does not include ≥90% stenosis.

Intraoperative graft patency by the HyperEye system and TFM

As a rule in this study, we used both the HyperEye system and TFM for intraoperative graft assessment in all patients. For intraoperative evaluation of graft patency and decisions about graft revision, TTFM was performed using MediStim BF 2004 (MediStim AS, Oslo, Norway). We used the following classification system by TFM as previously described.[3]

- Normal—mean flow >10 ml/min; PI <5; *and* DF >50%.
- Abnormal—mean flow <10 ml/min *or* PI >5 *or* DF <50%.
- If there was no quantifiable flow, a graft was deemed occluded.

As a rule in this study, decisions about graft revision were made according to TFM assessment. In addition, if there was retrograde flow (RF) during the systolic phase, a graft was deemed as having competitive flow.

The HyperEye system was used on the same grafts after TTFM. We defined graft occlusion as no fluorescence in the graft and a perfusion defect as no fluorescence in the perfusion coronary artery without a deep intramyocardial coronary artery. As a rule in this study, when the HyperEye system indicated graft occlusion or perfusion defects, we performed graft revision.

Baseline criteria related to ICG angiography does not exist; hence, we had to establish new criteria of the intraoperative evaluation. To make a standard assessment by the HyperEye system, we defined *normal graft* as continuous flow fluorescence on the graft and *functionally patent perfusion* as continuous, forward flow fluorescence in the perfusion territory that is dependent on the graft flow, and then the ICG fluorescence intensity of the target coronary artery is as same as the intensity of the graft. In addition, ICG fluorescence that started in the proximal portion of the graft body reached the distal anastomosis within five heartbeats.

We classified other visual images of the graft according to the following system:

- Competitive flow graft—retrograde or to-and-fro flow fluorescence on the anastomosis
- Irregular flow graft—forward but intermittent flow in the graft, excluding to-and-fro flow
- Slow flow—ICG fluorescence reaching from the proximal portion of the graft body to the distal anastomosis within five heartbeats
- Dissection, kinking, stenosis, or occlusion grafts

Abnormal perfusion was classified according to following system:

- Unfavorable perfusion—flow fluorescence in the perfusion territory is independent of the graft flow, or the fluorescence intensity of the target coronary artery is <70% compared with graft intensity
- No quantifiable perfusion because of deep intramyocardial coronary artery

To analyze the fluorescence intensity values, we have to make the static images of the perfusion coronary arteries, which is a limitation of this study.

Postoperative angiography

Our strategy of early postoperative graft assessment was based on scintigraphic outcomes; hence, thallium single-photon emission computed tomography (SPECT) scintigraphy was performed on all patients within 4 weeks after surgery. When thallium SPECT scintigraphy showed any type of ischemia, cardiologists performed early postoperative angiography. On the other hand, routinely conventional angiography was performed at 1 year after the surgery, even though no symptoms or signs of myocardial ischemia were observed.

Cardiologists evaluated each angiographic outcome independently, according to the following anatomical and physiological definitions. Anatomical definitions of graft failure are as follows: total occlusion, >75% or 50% stenosis; string-sign; and Fitzgibbon A, B, and O class (A = patent or stenosis <50%, B = stenosis >50%, O = total occlusion). Physiological parameters are TIMI flow 0, no perfusion; 1, minimal entry of dye; 2, partial perfusion; 3, normal perfusion.

Statistical analysis

All data were expressed as the mean ± standard deviation or as percentages. An unpaired Student's *t*-test was used to verify the significance of fluorescence intensity between the graft and the perfusion territory. Fisher's exact probability test was used to confirm the relation between the severity of the native coronary artery stenosis and to-and-fro flow fluorescence; and the kappa statistic was used to evaluate the agreement of TFM and the HyperEye system. Two-way contingency table analysis was used to calculate the effectiveness of a diagnostic criterion for some conditions (sensitivity and specificity).

Results

Patient population

We obtained the intraoperative graft flows and images in 51 patients from April 2007 to April 2009. The total of 189 distal anastomoses were constructed in 153 grafts. The average number of distal anastomoses was 3.7 ± 1.1 per patient. Baseline patient characteristics are shown in Table 1. The overall pattern of the conduits used were 69 in situ arterial grafts (45%), 8 free arterial grafts (8%), 43 individual SVGs (28%), and 33 sequential SVG bypasses (22%, the average number of anastomoses were 2.1 ± 0.3 per sequential graft). Anastomosis locations and graft designs are shown in Table 2.

Intraoperative graft assessment

Patent grafts

Both the HyperEye system and TFM indicated the patency in 129 of 153 grafts (84.3%). TFM showed the following values: mean flow (MF) 25 ± 3 ml/min, pulsatility index (PI) 2.2 ± 0.1, diastolic filling (DF) 74% ± 5%. The HyperEye system showed continuous flow fluorescence on the graft, continuous and forward flow fluores-

Table 1 Baseline characteristics of 51 patients

Average age (years)	70.4 ± 8.9
Male (%)	76
Acute coronary syndrome (%)	49
Coronary risk factors (%)	
Hypertension	43
Dyslipidemia	41
Diabetes	43
Smoking	27
CRF/HD	8
Prior CABG (%)	2
Urgent CABG (%)	33
Prior PCI (%)	24
Prior MI (%)	33
Off-pump CABG (%)	96
CABG + other cardiovascular surgery (%)	4
No. of diseased vessels (%)	
1 VD	2
2 VD	6
3 VD	29
LMT	
Only	8
1 VD	6
2 VD	4
3 VD	39
No. of distal anastomoses (per patient)	3.7 ± 1.1
IABP (%)	4

CABG, coronary artery bypass graft; CRF/HD, chronic renal failure/hemodialysis; IABP, intraaortic balloon pumping; MI, myocardial infarction; PCI, percutaneous coronary intervention; VD, vessel disease; LMT, left main trunk

Table 2 Anastomses: location and graft type

Parameter	No.	%
Distal anastomoses ($n = 189$)		
LAD lesion	78	41
Cx lesion	65	34
RCA lesion	46	24
Grafts ($n = 153$)		
ITA	63	41
Individual SVG	43	28
Sequential SVG	33	22
Free arterial graft	8	5
GEA	6	4

LAD, left anterior descending artery; Cx, circumflex artery; RCA, right coronary artery; ITA, internal thoracic artery graft; SVG, saphenous vein graft; GEA, gastroepiploic artery graft

cence in the perfusion territory that is dependent on the graft flow, and wide left ventricular perfusion. The fluorescence intensity of the target coronary artery was the same as the graft's intensity; ICG fluorescence reached from the proximal portion of the graft body to the distal anastomosis within five heartbeats.

In addition, when the native coronary artery stenosis was around 90% or greater (Fig. 2A), the HyperEye system did not capture the flow fluorescence through the narrow portion of the native coronary artery in the target lesion. On the other hand, when the native coronary artery stenosis was around 80% or less (Fig. 2B), the HyperEye system captured intermittent flow fluorescence through the narrow portion of the native coronary artery in the target lesion. Moreover, the flow fluorescence of the perfusion territory is dependent on the diastolic graft flow.

Functionally patent grafts with competitive flows

Competitive graft has a specific characteristic that is dependent on the graft type and the severity of the native coronary artery stenosis. The HyperEye system detected to-and-fro flow fluorescence in in situ arterial grafts only and did not detect it in aortocoronary (AC) bypass grafts. Moreover, when the native coronary artery stenosis was around 75% or less, to-and fro flow fluorescence was detected by the HyperEye system in almost all cases. For the severe stenosis group, in in situ arterial grafts the HyperEye system did not show to-and-fro flow fluorescence in 34 grafts and showed it in 8 grafts; and for the moderate stenosis group, in insitu arterial grafts the HyperEye system showed to-and-fro flow fluorescence in 11 grafts and did not show it in 3 grafts. Fisher's exact probability test confirmed the relations between the severity of the stenosis and to-and-fro flow fluorescence ($P < 0.001$), according to our classification system.

For 16 of 153 (10.5%) in situ arterial grafts the HyperEye system clearly visualized the flow competition on the anastomosis (Fig. 3) and TFM detected the retrograde waveform during the early systolic phase; MF was 19 ± 2 ml/min, PI was 3.0 ± 0.2, DF was 75% ± 6%, and the percentage of retrograde flow/total forward flow (%TRF) was 3.8% ± 1.4%. Both devices captured to-and-fro flow that was produced by the time delay running between the systolic wave onset through the native coronary and the systolic wave through the graft. We considered the baseline functionally patent assessment by the HyperEye system as the perfusion flow fluorescence was dependent on the diastolic graft flows. In the present study, the HyperEye system captured clearly ICG fluorescence in the perfusion territory that was dependent on the diastolic graft flow. We diagnosed those grafts as functionally patent with flow competition, and we did not perform graft revision.

Functionally patent grafts

For 4 of 153 grafts (2.6%), the HyperEye system indicated patency of the graft whereas TFM classified them as abnormal. TFM showed MF 6–10 ml/min, but the HyperEye system clearly captured antegrade and continuous perfusion fluorescence, which was dependent on the diastolic graft flows, in the target territory. Furthermore, the fluorescence intensity was the same as the graft's intensity with visual assessment and ICG fluorescence reached the distal anastomosis within five heartbeats. We diagnosed functionally patent grafts, and we did not perform graft revision.

Occlusive grafts

Both the HyperEye system and TFM detected an abnormality of the graft in 7 of 153 grafts (4.6%) (Fig. 4). Four of the seven grafts had no or slow flow fluorescence and no perfusion defects of the target lesions according to the HyperEye system. By TFM, there was no quantifiable flow, or the MF was <5 ml/min, or the PI was >10. Therefore we performed graft revision in those patients. After graft revision, these grafts were classified as a patent group. On the other hand, we did not perform graft revision for three of the seven in this group because of poor perfusion territory or mild native coronary artery stenosis.

Nonocclusive stenosis grafts

For 7 of the 153 grafts (4.6%), TFM indicated patency of the graft: MF 19 ± 6 ml/min, PI 1.8 ± 0.2, DF 72% ± 11%. In contrast, the HyperEye system suspected non-

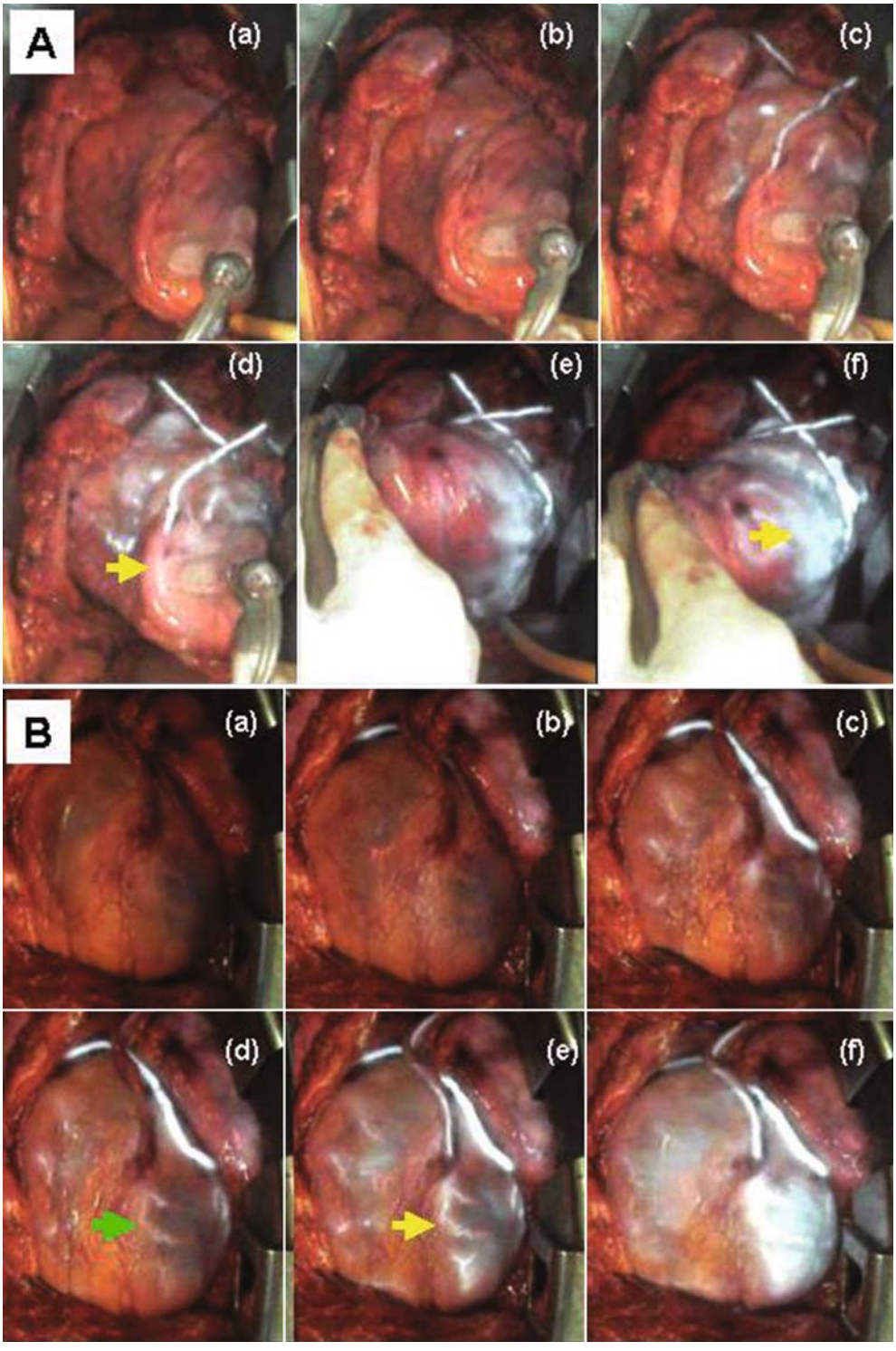

Fig. 2 Patent graft images with (**A**; **a**–**f**) severe native coronary artery stenosis and (**B**; **a**–**f**) moderate native coronary artery stenosis. **A** Left internal thoracic artery (LITA) to the left anterior descending coronary artery (LAD) and the right internal thoracic artery (RITA) to the posterolateral branch (PL). The HyperEye system indicated the patency of the graft and captured the graft-dependent perfusion fluorescence (*yellow arrows*). **B** The LITA to LAD, sequential saphenous vein graft (SVG) bypass to diagonal branch 1 (D1) and the PL branch, and sequential SVG bypass to 4PD and atrioventricular branch (4AV). The HyperEye system indicated patency of the graft and detected intermittent flow fluorescence (*green arrow*) through the native coronary artery and then graft-dependent perfusion fluorescence (*yellow arrow*)

occlusive graft failures: one reverse dissection of the ITA graft and six unfavorable perfusions in the target territory (Fig. 5). Unfavorable perfusions included any type of perfusion failure, including steal for the branch vessels, intermittent flow of the graft, or decreased ICG intensity in the perfusion territory. We did not perform graft revision for those patients because we did not yet know which type of nonocclusive failure assessment needs graft revision.

ICG fluorescence intensity analysis

When we diagnosed the patent and the functionally patent grafts with and without competitive flows, there

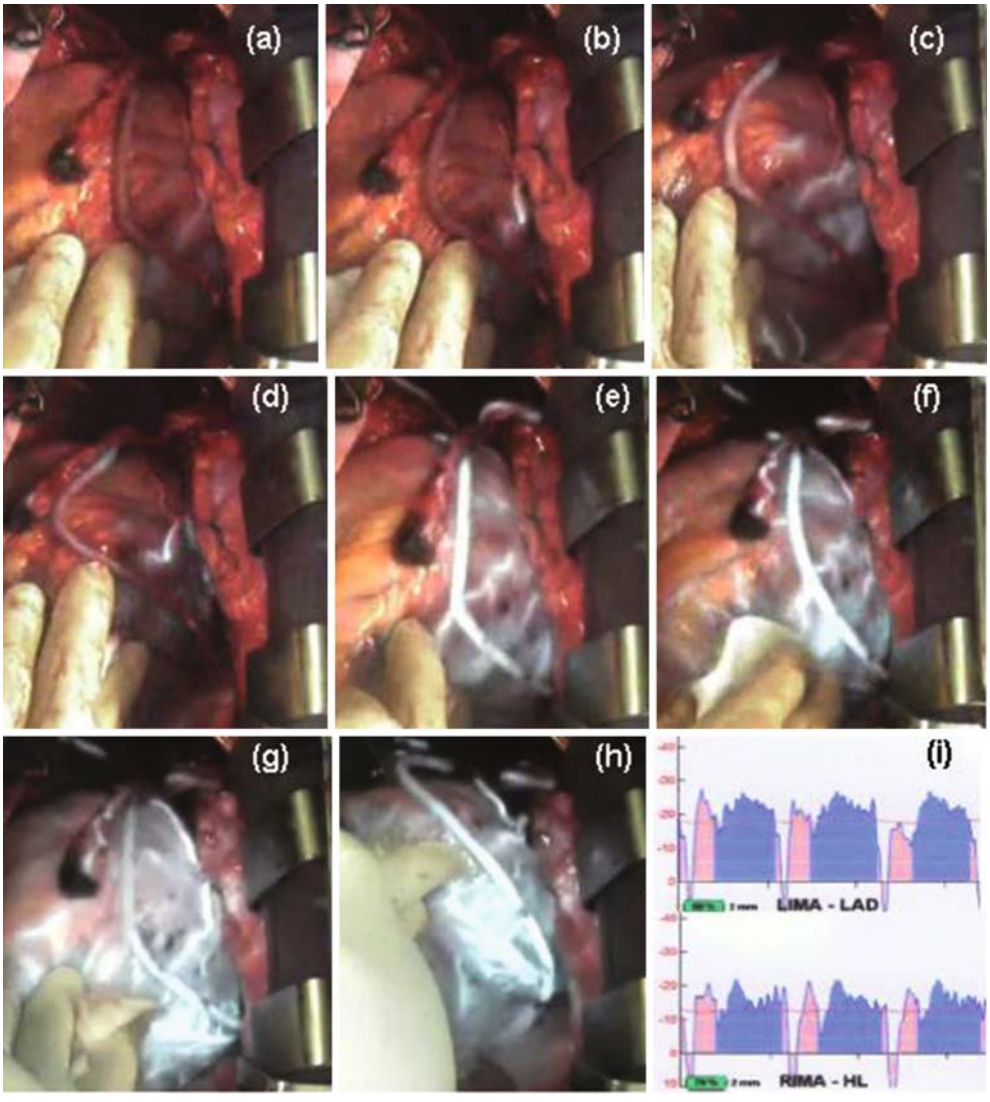

Fig. 3 Functionally patent graft with competitive flow images (**a–h**). LITA to LAD, RITA to the obtuse marginal branch (OM), and SVG to the D1 and PL branches. The HyperEye CCD camera captured to-and-fro flow (flow competition) on the anastomosis of the ITA grafts (**a–d**) and graft-dependent perfusion (**e–h**). Transit-time flowmetry detected the retrograde waveform during the early systolic phase (**i**)

was no difference in fluorescence intensity values between the graft and the target lesion (n = 139; 238 ± 19 vs. 226 ± 26 a.u, P = N.S). In contrast, when we diagnosed nonocclusive grafts by the HyperEye system, the fluorescence intensity values showed a significant difference between the graft and the target lesion (n = 7; 230 ± 26 vs. 156 ± 13 a.u, P = 0.02).

Evaluating agreement between the two devices

The HyperEye system and TFM showed a comparable assessment in 142 grafts (129 patent grafts, 16 functionally patent grafts with competitive flows, 7 occlusive grafts). In contrast, there was a different assessment in 11 grafts (4 functionally patent grafts, 7 nonocclusive grafts). The kappa statistic was weak, $\kappa = 0.18$, between TFM and the HyperEye system, which did not indicate evaluation of the agreement between two devices.

Angiographic outcome

According to our protocol for postoperative angiography, we obtained postoperative angiographic outcomes in 56 of 153 grafts (37%) until April 2009. Angiography indicated the patency of the graft in 49 grafts and showed graft failure in 7.

Although 56 grafts included 50 patent or functionally patent with and without competitive flows, 5 nonocclusive stenosis grafts, and 1 occlusive graft without graft revision, angiography and the HyperEye showed comparable graft patency (Fitzgibbon A and TIMI 3 on angiography) in 49 grafts and comparable graft failure (string-sign, Fitzgibbon B or O, and/or non-TIMI 3 on angiography) in 6 grafts. For only one graft did the HyperEye indicated the patency of the graft but angiography indicated graft occlusion. The sensitivity and specificity of the HyperEye system were 85.7% and 100%,

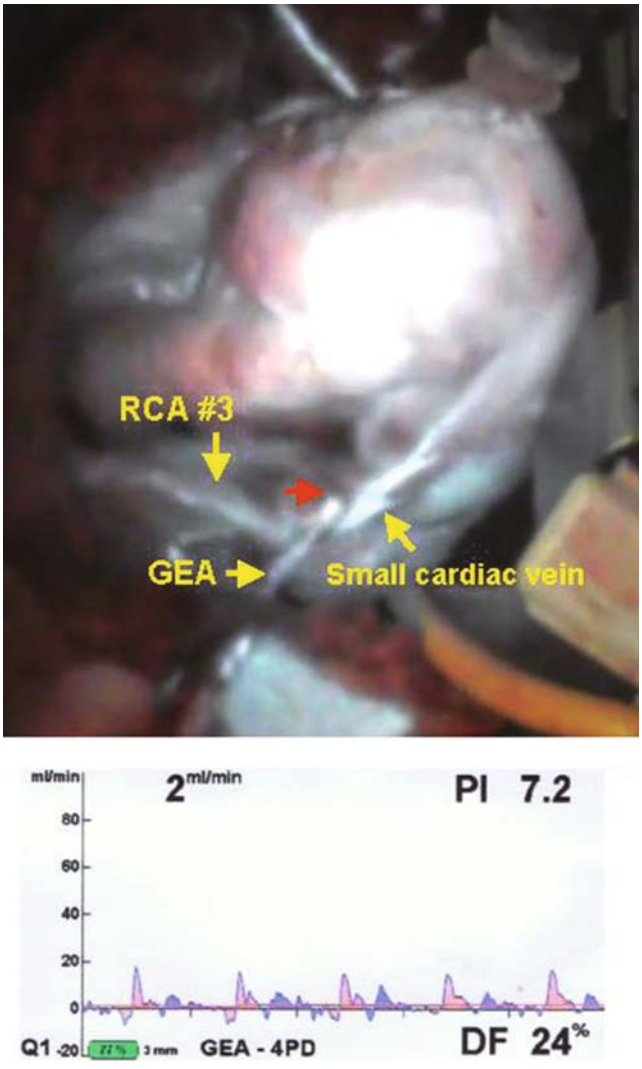

Fig. 4 Both the HyperEye and TFM systems detected graft occlusion. The right coronary artery (RCA) #2 has 75%–90% long stenosis. A gastroepiploic artery (GEA) to posterior descending artery (4PD) anastomosis was constructed (*red arrow*). The HyperEye CCD system did not capture the perfusion fluorescence in 4PD territory. We performed graft revision

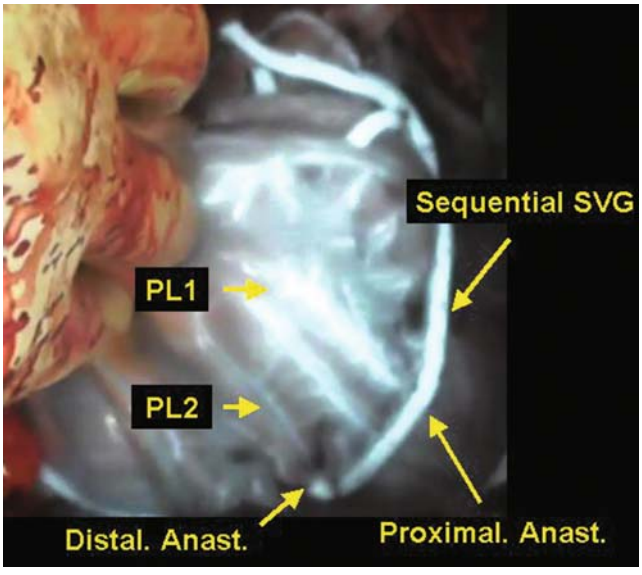

Fig. 5 Although transit-time flowmetry indicated patency of the graft (mean flow 19 ml/min, pulsatility index 1.6, diastolic filling 70%), the HyperEye system showed decreased fluorescence intensity between the proximal and distal portions in the sequential graft. *Anast*., anastomosis; *SVG*, saphenous vein graft; *PL*, posterolateral branch

respectively. On the other hand, for seven failing grafts on angiography, TFM showed patency in six grafts and no quantifiable flow in one. The sensitivity and specificity of TFM were 12.5% and 92.9%, respectively, in the preliminary diagnostic study.

Discussion

The ICG fluorescence imaging system is being used to verify intraoperative graft patency with visual images.[6–11] However, because of the main drawbacks of the SPY system—capturing ICG fluorescence by a monochromatic CCD camera and a short recording time—it is difficult to localize the target coronary artery and to capture the myocardial perfusion within 35 s.

The HyperEye system can simultaneous capture color and NIR images during ICG angiography and image the operative field with vivid, true colors, making it easy to verify the localization of the target coronary and myocardial perfusion (Figs. 2–5). The HyperEye system also is able to visualize any physiological perfusion, structural failures, and functional failures because of the long recording time.

The fluorescence images captured by the HyperEye system are characterized by a disparity in systolic and diastolic flow to the myocardium. The fluorescence image profile is explained by the beat-to-beat profiles of pressure and resistance as well as the flow profile detected by TFM.

The difference in the perfusion images of patent grafts is related to the severity of the native coronary artery stenosis. When the coronary artery stenosis is severe, the myocardial perfusion is dependent on the diastolic graft flows rather than the native coronary artery flows.[15,16] Here, the HyperEye system visualizes the graft-dependent perfusion only, as shown Fig. 2A. On the other hand, when the graft stenosis is severe but the native coronary artery pressure is greater than the graft pressure during the early diastolic phase,[15,16] the HyperEye system captures both the intermittent flow fluorescence through the narrow portion of the native coronary

artery and the graft-dependent perfusion, as shown Fig. 2B.

Furthermore, when the native coronary pressure is greater than the graft pressure during the early systolic phase, the HyperEye system captures both the intermittent flow fluorescence through the narrow portion of the native coronary artery and the back-flow fluorescence from the native coronary artery to the graft (i.e., the to-and-fro flow, as shown Fig. 4). To-and-fro and competitive flows are produced by the time delay running between the systolic wave onset through the native coronary and the systolic wave through the graft.[15,16] The to-and-fro and competitive flows detected by the HyperEye system are dependent on the graft type (in situ arterial graft) and the severity of the native coronary artery stenosis (did not include ≥90% stenosis site) in almost cases. Nakajima et al. defined competitive flow assessment by X-ray angiography as the target vessel was barely opacified from the ITA graft injection and the bypass graft was filled by retrograde flow from the native coronary injection that was a functionally patent graft.[17] According to this definition, when the HyperEye system captured both to-and fro flow and patent perfusion that is dependent on diastolic graft flow, based on those images we diagnosed a functionally patent graft. Hence, we believe that visualization of perfusion fluorescence using the HyperEye system has an advantage over TFM for intraoperative competitive flow assessment.

To evaluate nonocclusive graft failure, a limitation of the TFM measurement is that it does not provide a visual assessment of the stenosis. Cerrito et al. failed to detect a <50% narrowing anastomosis by TFM compared with the conventional techniques.[18] TFM gave only the local flow information of the graft within the area of probe and thus never revealed the quality of the CABG-induced restoration of myocardial perfusion in the area distal to the probe. Although TFM indicated the patency of the graft, the HyperEye system captured a reverse dissection and/or unfavorable perfusion in seven grafts owing to the decreased fluorescence intensity. When perfusion of the target territory was independent of the graft (e.g., the graft flow was stolen for the branch vessel), another graft was a source of the supply for perfusion in the target territory; and the HyperEye system was able to capture irregular flow fluorescence in the graft or a decrease in the density of the target territory, as shown by ICG fluorescence intensity analysis. Hence, we believe that the HyperEye system can visualize the decrease in fluorescence intensity, which is an advantage over TFM for assessing nonocclusive graft failures.

In the present study, the kappa statistic was too weak to indicate agreement of TFM and the HyperEye system. However, do we need an evaluation of the agreement between two devices? The criteria of the patency assessment using the HyperEye system included a perfusion assessment that was severe compared with that of TFM alone. Therefore, we think that we do not need to evaluate the agreement between the two devices.

A diagnostic test study using the SPY system has already performed by Desai et al. The sensitivity and the specificity of that system for detecting >50% stenosis or occlusion were 83.3% and 100%, respectively.[11] We outlined a preliminary diagnostic test study in the results section. For seven failing grafts detected by angiography, the HyperEye system detected an abnormality in only six of the seven, and TFM detected an abnormality in only one. Hence, the sensitivity of the HyperEye system is greater than that of TFM (85.7% vs. 12.5%) and of the SPY study.

These findings speculate that the HyperEye system may become a useful graft assessment tool because of its ability to detect the details of the graft and perfusion failure.

Limitations and further aspects of the study

Our strategy of early postoperative graft assessment was based on scintigraphic outcomes reported by cardiologists, and good angiographic outcomes were relatively low, 37% of all grafts, until April 2009. We did not describe the details of the angiographic preparation in the present report. To confirm a diagnostic study, we have to perform postoperative angiography for all patients. As a further aspect of this study, we calculated the sensitivity and specificity of both the HyperEye system and TFM compared with conventional angiography for all patients. Furthermore, we established our own criteria for intraoperative graft assessment based on the fluorescence intensity analysis to predict further graft failures.

Conclusion

The HyperEye system visualized ICG-enhanced structures against a background of natural myocardial color, which improved the ability to identify abnormalities in flow and perfusion. Using both the HyperEye system and TFM for intraoperative graft assessment, we can evaluate the quality of the graft more clearly than when it is done by TFM alone. Our new device could become a useful tool for intraoperative graft assessment.

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